

vehicle, the micro particles of the composition further being of a designed average particle size distribution and characterized by a rough surface having a plurality of surface irregularities generally randomly formed therein, such that the effects of average particle size and average particle surface roughness cooperate in combination in an autogenous manner to essentially prevent loss of the micro particles from any injection site, the particles remaining to be incorporated as long-term tissue augmentation.

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(cont.)

32. A method as defined in claim 31 wherein the composition is injected into a submucosal space selected from the bladder-urethral junction, the esophageal-gastric junction and the gastric-pyloric junction using a plurality of spaced injection sites.

33. A method as defined in claim 31 wherein the surface irregularities of the micro particles describe indentations, cavities and pores forming a very irregular surface and openings within the particles, the micro particles having an average unidimensional particle size generally between 30 and 3000 microns with the dimensions of the indentations, cavities and pores within the particles being generally in a range between 10 angstroms and 500 microns.

34. A method as defined in claim 31 wherein the micro particles possess an average unidimensional particle size above 60 microns.

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*(Cont)*

35. A method as defined in claim 31 wherein the micro particles possess an average unidimensional particle size in the range of from about 80 microns to about 600 microns.

36. A method as defined in claim 31 wherein the micro particles possess an average unidimensional particle size in the range of from about 100 microns to about 600 microns.

37. A method as defined in claim 36 wherein the resilient material is a polysiloxane and wherein the physiological vehicle comprises polyvinylpyrrolidone.

38. A method as defined in claim 37 wherein the resilient material is polydimethylsiloxane.

39. A method as defined in claim 34 wherein the composition is injected into a submucosal space selected from the bladder-urethral junction, the esophageal-gastric junction and the gastric-pyloric junction using a plurality of spaced injection sites.

40. A method as defined in claim 31 wherein the composition is injected under the intravesical portion of the ureter using a plurality of spaced injections.

41. A method as defined in claim 34 wherein the composition is injected under the intravesical portion of the ureter using a plurality of spaced injections.

42. A method as defined in claim 39 wherein the amount of the composition injected per site is from about 1.0 to about 5.0 cc.

43. A method as defined in claim 40 wherein the amount of the composition injected per site is from about 1.0 to about 5.0 cc.

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44. A method for long-term treatment of incontinence comprising the steps of making a plurality of spaced injections into the submucosal layer of the urethra of a composition comprising an amount of relatively soft, malleable, elastic, biologically compatible prosthetic micro particles dispersed in a non-retentive compatible physiological vehicle, the micro particles of the composition further being of a designed average unidimensional particle size distribution between 30 and 3000 microns, and characterized by a rough surface having a plurality of surface irregularities generally randomly formed therein, characterized by indentations, cavities and pores forming openings upon the surface of the particles, with the dimensions of the indentations, cavities and pores being generally in a range between 10 angstroms and 500 microns, such that the effects of average particle size and average particle surface roughness cooperate in combination in an autogenous manner to essentially prevent loss of the micro particles from any injection site, the particles remaining to be incorporated as long-term tissue augmentation.

45. A method as defined in claim 44 wherein the micro particles possess an average unidimensional particle size in the range of from about 100 microns to about 600 microns.

46. A method is defined in claim 45 wherein the micro particles comprise a polysiloxane material.

47. A method as defined in claim 45 wherein the resilient material is a polysiloxane and wherein the physiological vehicle comprises a polyvinylpyrrolidone.

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(Cont)

48. A method for long-term treatment of gastric reflux comprising the steps of making a plurality of injections at spaced sites into the appropriate submucosal space selected from the esophageal-gastric junction and gastric-pyloric junction a composition comprising an amount of relatively soft, malleable, elastic, biologically compatible micro particles dispersed in a non-retentive compatible physiological vehicle, the micro particles of the composition further being of a designed average unidimensional particle size distribution between 30 and 3000 microns, and characterized by a rough surface having a plurality of surface irregularities generally randomly formed therein, characterized by indentations, cavities and pores forming openings upon the surface of the particles, with the dimensions of the indentations, cavities and pores being generally in a range between 10 angstroms and 500 microns, such that the effects of average particle size and average particle surface roughness cooperate in combination in an autogenous manner to essentially prevent loss of the micro particles from any injection site, the particles remaining to be incorporated as long-term tissue augmentation.

49. A method as defined in claim 48 wherein the micro particles possess an average unidimensional particle size in the range of from about 100 microns to about 600 microns.

50. A method is defined in claim 49 wherein the micro particles comprise a polysiloxane material.

51. A method as defined in claim 49 wherein the physiological vehicle comprises a polyvinylpyrrolidone.

52. In a method for treating urological and gastric disorders comprising the step of injecting submucosally or peri-urethrally into tissue at at least one injection site a composition comprising an effective amount of micro particles dispersed in a compatible physiological vehicle, the improvement comprising the steps of:

~~selecting relatively soft, resilient, malleable, biologically compatible micro particles consisting essentially of a polysiloxane material, the micro particles having an average undimensional particle size above 60 microns and having a highly irregular particle surface configuration including indentations, cavities and pores generally randomly formed therein such that the effects of average particle size and irregular particle surface cooperate in an autogenous manner to essentially prevent loss of the micro particles from an injection site;~~

~~selecting a compatible physiological vehicle that will promote injection of the micro particles but once injected is non-retentive of the particles.~~

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**REMARKS**

In accordance with the above amendments, Claims 1-30 in the parent application have been canceled, without prejudice, and